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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,739	08/25/2003	Manuel Guzman Pastor	A34700 PCT USA-I	2301
21003	7590	10/12/2007	EXAMINER	
BAKER BOTTS L.L.P.			ANDERSON, JAMES D	
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44TH FLOOR			ART UNIT	
NEW YORK, NY 10112-4498			PAPER NUMBER	
			1614	
			NOTIFICATION DATE	
			DELIVERY MODE	
			10/12/2007	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DLNYDOCKET@BAKERBOTTSCOM

Office Action Summary

Application No.

10/647,739

Applicant(s)

GUZMAN PASTOR ET AL.

Examiner

James D. Anderson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/958,960.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2 sheets.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

CLAIM 16 IS PRESENTED FOR EXAMINATION

Applicants' arguments and Information Disclosure Statement filed 8/8/2007 have been received and entered into the application. No claims have been amended, cancelled, or added. Also, as reflected by the attached, completed copy of USPTO Form 1449 the cited references have been considered.

Applicants' arguments, filed 8/8/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Applicant's arguments filed 8/8/2007 with respect to the 35 U.S.C. rejection of claim 16 have been fully considered but they are not persuasive. Applicants submit that the *in vitro* study of Δ^9 -tetrahydrocannabinol inducing apoptosis in C6 glioma cells does not render the instantly claimed method of treating glioblastomas obvious. At best, Applicants assert, Sanchez provides an opportunity to try their hypothesis, which is "not the standard for a *prima facie* case of obviousness" (page 4 of Response). However, the recent Supreme Court decision in *KSR International Co. v. Teleflex Inc.* supports the "obvious to try" standard when it relates to a finite number of predictable solutions. In such cases, a claim is deemed obvious because "a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill

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and common sense.” Further, Applicants’ arguments that one skilled in the art would not have any reasonable expectation of success “that a compound inducing in vitro apoptosis would do the same when administered to an in vivo model given the differences in environment” is not persuasive because the courts have held that *in vitro* assays are reasonable predictive of activity *in vivo*. The mechanism of action *in vitro* versus *in vivo* is not at issue here. The question is whether one skilled in the art, having knowledge that Δ^9 -tetrahydrocannabinol induces apoptosis in C6 glioma cells (Sanchez *et al.*) and that glioma cell lines are used as models of glioblastoma multiforme when implanted in rat brains (Uesugi *et al.*), would have been motivated to try Δ^9 -tetrahydrocannabinol for the treatment of glioblastomas. In this case, as set forth in the previous Office Action and reiterated below, one of ordinary skill in the art would be motivated to do so and would have been imbued with at least a *reasonable* expectation of success. While the references submitted by Applicants demonstrate that the treatment of glioblastomas with agents that inhibit the growth of or induce apoptosis is the *in vitro* setting is not 100% predictable, such a showing does not foreclose the reasonable expectation standard.

Accordingly, the rejection of claim 16 as being obvious over Sanchez *et al.* in view of Uesugi *et al.* is maintained for the reasons of record and reiterated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 16 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Sanchez *et al.* (FEBS Letters, 1998, vol. 436, pages 6-10) in view of Uesugi *et al.* (Acta Neuropathol., 1998, vol. 96, pages 351-356).

The instant claim recites a method of treating glioblastomas comprising administering Δ^9 -tetrahydrocannabinol (Δ^9 -THC) or Δ^8 -tetrahydrocannabinol (Δ^8 -THC).

Sanchez *et al.* disclose that Δ^9 -THC induces apoptosis in C6 glioma cells (Abstract; Figures). The authors suggest that the challenge of C6.9 cells to cannabinoids may be a useful model to study the molecular mechanisms involved in apoptosis in cells of glial origin (page 9, right column).

C6 glioma cells are art-recognized as a model of glioblastomas. For example, Uesugi *et al.* discloses the use of a rat glioma cell line (C6) as a rat glioma model (Abstract; page 351). Apoptosis of glioma cells is induced by the administration of several agents, including anti-tumor drugs (*id.*). C6 glioma cells are traditionally used as a model of glioblastoma multiforme when implanted in rat brains (page 354).

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The instantly claimed method of treating glioblastomas by administering Δ^9 -THC or Δ^8 -THC would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Sanchez *et al.* demonstrate that Δ^9 -THC induces apoptosis in C6 glioma cells. As such, the skilled artisan would have been motivated to use Δ^9 -THC to treat glioblastomas given the fact that C6 gliomas cells were recognized in the art as a model of glioblastoma growth, invasion and metastases. Further, the skilled artisan would have been imbued with at least a reasonable expectation that a compound that induces apoptosis of C6 glioma cells *in vitro* would also be effective in treating a glioblastoma *in vivo*.

Accordingly, the claim is deemed properly rejected under 35 U.S.C. § 103 as being *prima facie* obvious over the cited references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


James D. Anderson
Patent Examiner
AU 1614

October 2, 2007


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER